

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA**

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION)))))))	MDL No. 16-2740 SECTION: “H” (5)
This document relates to: Elizabeth Kahn, 16-17039))	

ORDER AND REASONS

Before the Court is Plaintiff’s Motion to Exclude Testimony of Dr. Azael Freites-Martinez (Doc. 11355). The Court held oral argument on the Motion on December 14, 2020. For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation (“MDL”) are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,¹ that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, “Sanofi” or “Defendants”). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for 2021.²

In the instant Motion, Plaintiff Elizabeth Kahn, the second bellwether plaintiff, moves to exclude the testimony of Dr. Azael Freites-Martinez. Dr.

¹ Docetaxel is the generic version of Taxotere.

² The second trial was continued due to the COVID-19 pandemic.

Freites-Martinez is an onco-dermatologist, and Sanofi intends to call him as an expert witness at trial. Sanofi opposes Plaintiff's Motion.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.³

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*⁴ and *Kumho Tire Co. v. Carmichael*.⁵ The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.⁶ After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.⁷ As the

³ FED. R. EVID. 702.

⁴ 509 U.S. 579 (1993).

⁵ 526 U.S. 137 (1999).

⁶ *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 799 (E.D. La. 2011). *See also* *Wilson v. Woods*, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").

⁷ *See* *United States v. Valencia*, 600 F.3d 389, 424 (5th Cir. 2010). *See also* *Wellogix, Inc. v. Accenture, L.L.P.*, 716 F.3d 867, 881–82 (5th Cir. 2013).

“gatekeeper” of expert testimony, the trial court enjoys broad discretion in determining admissibility.⁸

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert’s testimony is valid.⁹ The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.¹⁰ Courts should exclude testimony based merely on subjective belief or unsupported speculation.¹¹ Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.¹² “Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”¹³ After assessing reliability, a court evaluates relevance.¹⁴ In doing so, a court must determine whether the expert’s reasoning or methodology “fits” the facts of the case and will thereby assist the trier of fact in understanding the evidence.¹⁵

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony’s probative value substantially outweighs its prejudicial effect.¹⁶

LAW AND ANALYSIS

In her Motion, Plaintiff argues that (1) Dr. Freitas-Martinez does not have enough experience to qualify him as an expert, and (2) that Dr. Freitas-

⁸ *Wellogix*, 716 F.3d at 881.

⁹ *See Daubert*, 509 U.S. at 592–93.

¹⁰ *See Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

¹¹ *See Daubert*, 509 U.S. at 590.

¹² *See id.* at 596.

¹³ *Id.*

¹⁴ *Burst v. Shell Oil Co.*, 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).

¹⁵ *Id.*

¹⁶ FED. R. EVID. 703.

Martinez is not qualified to offer case-specific opinions regarding Plaintiff Kahn's hair loss. The Court will address each argument in turn.

I. Dr. Freitas-Martinez's Experience

Plaintiff argues that the Court should not allow Dr. Freitas-Martinez to offer the following opinions given his level of experience:

- His opinion that the widespread use of systemic anticancer agents, their myriad combinations, and underreporting of hair disorders make it difficult to establish the true cause of chemotherapy-induced alopecia;
- his opinion that the mechanism of Taxotere-induced alopecia is unclear because damage to hair follicles by taxanes has not been elucidated; and
- his opinion that a full medical history must be obtained and analyzed to properly diagnose alopecia.¹⁷

Plaintiff emphasizes that Dr. Freitas-Martinez only recently finished his residency in 2016 and that he has less than one year of part-time experience working as an onco-dermatologist. Plaintiff acknowledges that Dr. Freitas-Martinez has published articles relating to alopecia, but she argues that Dr. Freitas-Martinez published these articles while working under the supervision of another doctor, Dr. Mario Lacuoture. Plaintiff suggests that Dr. Lacuoture is largely responsible for the articles. In response, Sanofi emphasizes that the parties discussed and presented the work of Dr. Freitas-Martinez to the jury in the first bellwether trial, the *Earnest* trial. Sanofi argues that Rule 702 does not impose an age requirement and notes that Dr. Antonella Tosti, one of Plaintiff's experts, testified that Dr. Freitas-Martinez is an expert regarding chemotherapy regimens and persistent alopecia.

¹⁷ See Doc. 11355-1 at 4.

The Court rejects Plaintiff's argument that Dr. Freitas-Martinez has insufficient experience to qualify as an expert. From 2016 to 2018, Dr. Freitas-Martinez participated in a fellowship and treated patients alongside Dr. Mario Lacouture, who is an established expert in dermatologic adverse events associated with cancer therapies.¹⁸ As a research fellow for Dr. Lacouture, Dr. Freitas-Martinez focused on hair disorders, and he saw hundreds of patients.¹⁹ With Dr. Lacouture, he authored several publications addressing persisting hair loss after treatment with docetaxel and other drugs. In addition to this, he has worked with Plaintiff's expert, Dr. Tosti, who called him an expert.²⁰ Currently, he is leading a clinical trial investigating persistent hair loss and chemotherapy. Considering his close work with Dr. Lacouture and his focus on hair disorders, Dr. Freitas-Martinez has specialized knowledge regarding

¹⁸ Plaintiff admits as much. At oral argument, Plaintiff's counsel acknowledged that Dr. Lacouture is a Sloan Kettering onco-dermatologist with a very specialized practice. Doc. 12039 at 7. Counsel noted that Dr. Tosti testified that Dr. Lacouture is "a leading authority in the world." *Id.* at 11. Also, in her briefing, Plaintiff noted that Dr. Tosti, "is a lot more akin to Dr. Lacouture than Dr. Freitas-Martinez." Doc. 11497 at 8.

¹⁹ Doc. 11415 at 4; Doc. 12039 at 21.

²⁰ Doc. 11415-7 at 3.

- Q: [I]s there anything in this book in particular about persistent alopecia in chemotherapy regimens?
- A: Yes. There is a chapter on hair disorders due to cancer medications, and there is a -- permanent alopecia is discussed.
- Q: Who wrote that chapter?
- A: I wrote that chapter with Freitas Martinez.
- Q: He's the doctor that appeared on a couple of CME articles, I believe?
- A: Yes, CEs.
- Q: Did he primarily write that chapter or did you?
- A: He did the draft, and then I corrected the chapter.
- Q: Do you think that he's an expert with regard to chemotherapy regimens and persistent alopecia?
- A: I think somehow, he is because he wrote a lot on status, this topic. He's a young doctor, and this is more a review because it's a book.

chemotherapy-induced alopecia. His few years of experience render him qualified, and the Court sees no reason to exclude his testimony.

II. Dr. Freites-Martinez's Case-Specific Opinions

Plaintiff argues that the Court should not allow Dr. Freites-Martinez to opine that Plaintiff Kahn “suffers from persistent alopecia with a predominant androgenetic pattern after different chemotherapies and endocrine therapy” and that this androgenetic pattern “suggests a strong Tamoxifen influence.”²¹ Plaintiff emphasizes that Dr. Freites-Martinez is not licensed in the United States and did not examine Plaintiff Kahn in person. Plaintiff argues that Dr. Freites-Martinez did not apply a proper methodology, and she avers that because Sanofi has not proven general causation, Dr. Freites-Martinez cannot opine on specific causation.²² In response, Sanofi notes that Dr. Tosti does not report taking or passing any licensing exam in the United States, and unlike Dr. Freites-Martinez, Dr. Tosti never received any training in the United States but received all her training overseas. Sanofi further avers that Dr. Freites-Martinez has a sound basis for his opinions.

Federal Rule of Evidence 702 does not impose a professional license requirement.²³ Dr. Freites-Martinez, therefore, need not be licensed in the United States to opine on Plaintiff Kahn's hair loss.²⁴ Indeed, Dr. Freites-Martinez is currently a practicing dermatologist in Spain and the Canary Islands. He testified that he treats “cancer patients about their adverse events

²¹ Doc. 11355-1 at 6.

²² Specifically, Plaintiff's counsel made this statement at oral argument: “[N]obody proves general causation and you don't get to jump over that hurdle and just go to talk about specific causation if you have alleged and taken on the burden of proving it.” Doc. 12039 at 31.

²³ *Malbrough v. State Farm Fire & Cas. Co.*, 1996 WL 565819, *2 (E.D. La. Sept. 27, 1996) (“State licensing requirements do not automatically bar testimony by an expert witness in federal court—the expertise of the witness is measured by knowledge, skill, experience, training or education.”).

²⁴ As Sanofi notes, there is no evidence showing that Dr. Tosti is licensed in the United States, yet she has provided specific causation opinions in this MDL.

on the cancer therapy, especially hair problems in cancer patients.”²⁵ Considering this and his work with Dr. Lacouture discussed above, Dr. Freitas-Martinez is qualified to opine on Plaintiff Kahn’s hair loss.

Next, the Court rejects Plaintiff’s argument that before offering evidence on specific causation, Sanofi is required to prove general causation. For the reasons provided in its opinion on Plaintiff’s Motion to Exclude Testimony of John Glaspy, M.D., this argument falls flat.²⁶ In addition, the Court finds it inconsequential that Dr. Freitas-Martinez did not examine Kahn in person. In his report, Dr. Freitas-Martinez wrote as follows:

I have reviewed the clinical chart of the patient Ms. Elizabeth Kahn. . . . I have received documentation regarding relevant clinical data, including clinical images and notes of the dermatologic examinations performed on September 4, 2020 by Dr. Antonella Tosti and September 22, 2020 by Dr. Mamina Turegano, who were able to conduct in-person evaluations of the patient. I have further reviewed the expert reports of Drs. Tosti and Curtis Thompson, and testimony of Drs. Tosti and Thompson, as well as candid photographs of Ms. Kahn and her family members. . . . I base my opinions on my review of these materials, as well as relevant medical literature and documents and my training, experience and research as a dermatologist specialist in hair disorders in cancer patients.²⁷

He further indicates that he conducted a differential diagnosis, and he provides a thorough analysis explaining his work. The Court finds, then, that Dr. Freitas-Martinez has based his opinions on sufficient facts and data. The Court

²⁵ Doc. 11415 at 8.

²⁶ See Doc. 11780. (“Plaintiff Kahn bears the burden of proving that Taxotere caused her injury, and she must prove both general and specific causation.”). See also Doc. 11684 (Order and Reasons on Plaintiff’s Motion for Partial Summary Judgment on Affirmative Defenses Concerning Alternative Causes).

²⁷ Doc. 11415-1 at 16.

does not see how his failure to conduct an in-person examination has affected the reliability of his opinion, and Plaintiff will have the opportunity to explore this before the jury on cross-examination.

Although the Court finds that Dr. Freitas-Martinez is qualified to offer the opinions in his report, the Court notes that Sanofi has designated several experts to testify on the issue of specific causation. The Court will not allow Sanofi to offer cumulative testimony. Sanofi will need to streamline its evidence on this issue.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Testimony of Dr. Azael Freitas-Martinez (Doc. 11355) is **DENIED**.

New Orleans, Louisiana, this 7th day of April, 2021.

A handwritten signature in black ink, appearing to read "Jane Triche Milazzo", written over a horizontal line.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE